

Remarks

Applicant expresses appreciation to the Examiner for consideration of the subject patent application. This Response is in reply to the Office Action mailed January 29, 2007. Claims 1-24 were pending, with claims 12-16 and 20-24 being currently withdrawn from consideration. Claims 1-11 and 17-19 were rejected under 35 U.S.C. § 103(a).

Claims 1-24 remain in the application, with claims 12-16 and 20-24 being currently withdrawn and claims 1-11 and 17-19 pending for consideration at this time. No claims have been added, canceled or amended herein.

Election/Restrictions

Applicant affirms the earlier-made election to prosecute the invention identified by the Examiner as Group I, claims 1-11 and 17-19. Claims 12-16 and 20-24 have been withdrawn from consideration.

Claim Rejections - 35 U.S.C. § 103

Claims 1-11 and 17-19 (including independent claims 1, 7 and 17) were rejected under 35 U.S.C. § 103 as being unpatentable over Cosman (U.S. Patent No. 6,419,680) in view of Rini (U.S. Patent Application No. 2003/0181794).

While Applicant is confident that the Examiner is well acquainted with the requirements necessary to establish a *prima facie* case of obviousness, it is thought prudent to briefly review the required elements. Specifically, in order to meet the burden of establishing a *prima facie* case of obvious, the Patent Office must show that:

1) each and every element of the invention as set forth in the claims is taught or suggested by the reference as modified; 2) that there is sufficient motivation contained in the reference itself or the knowledge of one of ordinary skill in the reference to modify or combine the reference; and 3) that one of ordinary skill in the art would find a sufficient likelihood of successfully making the modification or combination asserted.

Applicant respectfully submits that the Examiner has not satisfied these requirements with respect to the asserted rejections. With regard to all of the independent claims collectively (e.g., claims 1, 7, and 17), Applicant submits that elements 2) and 3) above are not satisfied by Rini and Cosman. Consequently, a *prima facie* case of obviousness has not been established.

Specifically, to the extent each of the limitations of the independent claims are taught by either Rini or Cosman (a proposition Applicant expressly refutes), the combination of Rini and Cosman is improper as there is not sufficient motivation contained in either of these references (individually or collectively), or the knowledge of one of ordinary skill in the art, to modify or combine the reference; and ii) one of ordinary skill in the art would not find a sufficient likelihood of successfully making the modification or combination asserted.

The Rini and Cosman references teach devices that are very different in design and purpose. While the Cosman device may be used in similar applications as the present device, the Rini device is not at all related to the present invention. The present invention is an external medical imaging marker for use in imaging procedures, such as X-Ray procedures, CT Scans, etc. The present devices are removably attached to a patient's skin to serve as fiduciary markers. The Rini device is an

implantable sensor housing and sensor unit that is intended to be implanted within a patient's body for a period of at least four weeks (see the Abstract of Rini). The primary purpose of the Rini device is to serve as a wireless sensing unit and is only off-handedly described as being capable of use as a fiduciary marker. One of ordinary skill in the art would not look to Rini for suggestions on modifying Cosman, due to the very different natures of the Rini and Cosman devices and the very different manner in which the Rini and Cosman devices are utilized.

As such, Applicant respectfully submits that Rini and Cosman are not properly combined to establish a *prima facie* case of obviousness and requests that the rejection be withdrawn.

As to each of the independent claims individually, claim 1 includes the limitations of:

A medical imaging marker, comprising:
a marking body, having a predetermined shape, the marking body including an at least partially radiopaque material selected from the group consisting of: silica; silicates; soda-lime glass; and leaded glass; and
an attachment substrate, on which the marking body is disposed, the attachment substrate including means for removably attaching the marker to a patient's body.
(Emphasis added).

Thus, claim 1 requires a medical imaging marker with a body including a specified material (e.g., silica; silicates; soda-lime glass; and leaded glass). This limitation is not taught or suggested by either the Rini or the Cosman reference. In

those portions of Rini in which the Rini device is off-handedly described as capable of use with imaging systems (principally Paragraphs 0120-0121 of Rini), Rini indicates that the "radio-opaque materials may include ferrite material or radiopaque epoxies, coatings, inks, thin-films, paints, tapes, strips and the like." There is no indication that the embodiment of the Rini device that might be used with imaging systems is formed from "silica; silicates; soda-lime glass; and leaded glass," as claimed in the present invention. Rini is clearly listing a collection of known marking devices that can be added to his device, and nowhere indicates that these devices are formed from the materials claimed by Applicant.

Cosman, of course, similarly fails to teach or suggest the use of "silica; silicates; soda-lime glass; and leaded glass," as claimed in the present invention. Cosman teaches, rather, the use of only known marker materials including "copper sulfate or, simply, water." (Cosman, Column 3, line 38).

As such, the limitation of an imaging marker having a body formed from "silica; silicates; soda-lime glass; and leaded glass" is not taught by either reference asserted in the Office Action. Accordingly, independent claim 1 is patentable over the combination of Rini and Cosman.

In addition, dependent claim 4 includes the limitation of "[t]he predetermined shape [being] a substantially spherical shape." This limitation is not taught or suggested by Rini or Cosman. The Rini device is obviously cylindrical in shape. The Cosman device is, at best, characterized as a dome shape. Neither of these shapes in "substantially spherical," as positively claimed in dependent claim 4.

Independent claim 7 includes the limitations of:

A system of medical imaging markers having varying radiopaqueness, comprising:

at least two medical imaging markers, each marker including an at least partially radiopaque marking body disposed upon an attachment substrate;

each marking body exhibiting a visually identifiable color that is different from a visually identifiable color exhibited by another marking body; and

each marking body having an operable characteristic that is different from another marking body of the system.

(Emphasis added)

Thus, independent claim 7 requires a system with at least two markers, each of which exhibits a visually identifiable color that is different from one another: and each of the at least two markers must have an operating characteristic that is different from the other. Contrary to the assertion in the Office Action, Cosman does not teach these limitations. Instead, Cosman indicates:

The variation, for example, may include sets of fiducial markers, each having a different distinguishing feature such as size, color, shape, material, image enhancement, indexing dots, rings, patterns, qualities, etc. This would allow putting many on the patient at different points on the skin to track the stereotactic calibration, mapping, etc. The multiple numbers could be supplied as kits for this purpose, sterile packaged and ready to apply.

(Cosman, Column 6, lines 15)

This language from Cosman does not teach that each of the markers has a different color and a different operating characteristic. In fact, Cosman teaches away

from the presently claimed concept, stating “[the variation] would allow putting many on the patient at different points on the skin . . .” Clearly, the use of many markers in conjunction with each other indicates that the operating characteristic of each marker is the same. Otherwise, no usable stereotactic calibration or mapping data could be obtained from such a procedure.

Accordingly, the limitations of independent claim 7 are not found in either of Rini or Cosman. Claim 7 is thus patentable over the combination of Rini and Cosman.

Independent claim 17 includes the limitations of:

A medical imaging marker, comprising:
a marking body, exhibiting a visibly identifiable color which is associated with an operable characteristic of the marker; and
an attachment substrate, on which the marking body is disposed, the attachment substrate including means for removably attaching the marker to a patient's body.
(Emphasis added)

This limitation is also not taught or suggested by Rini or Cosman. While Rini states that different sizes, colors or shapes, etc., could be imparted to his sensors, he does not teach or suggest associating a visibly identifiable color with an imaging marker and associating the color with an operable characteristic of the marker.

Examples of the use of this concept with the present invention are provided in, among others, Paragraph 0034, where it is indicated that the different colors can correspond to different radiopacities, or different applications (e.g., CAT, MRI, PET, etc.). Thus, a medical professional may be provided with a series of the present markers, each having a different visibly identifiable color, and the professional could

determine at a glance which marker to use with a particular medical procedure. This advantage is not provided by the Cosman device.

In summary, Applicant respectfully submits that the Rini and Cosman references are not properly combined under 35 U.S.C. § 103 due to the wide variance of Rini from the purpose and design of the present invention and the purpose and design of the Cosman device (which results in a lack of motivation to combine the references and no likelihood of successfully combining them).

Furthermore, even were such a combination proper, each and every element of independent claims 1, 7 and 17 is not found in the Rini or Cosman references, either individually or combined.

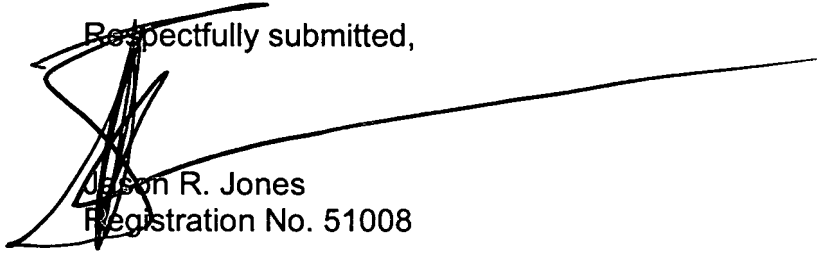
Conclusion

In light of the above, Applicant respectfully submits that pending claims 1-11 and 17-19 are in condition for allowance. Therefore, Applicant requests that the rejections and objections be withdrawn, and that the claims be allowed and passed to issue. If any impediment to the allowance of these claims remains after entry of this Response, the Examiner is strongly encouraged to call the undersigned at (801) 566-6633 so that such matters may be resolved as expeditiously as possible.

No claims have been added herein. A one-month extension of time is necessary to timely file this response. Check No. _____ is submitted herewith for the one month extension. The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Response to Deposit Account No. 20-0100.

DATED this 29th day of May, 2007.

Respectfully submitted,



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